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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 09/627,321  | 07/27/2000  | Ludger Dinkelborg    | SCH 1718 C1             | 2532             |
| 23599   | 7590        | 09/26/2002           | EXAMINER                |                  |
| MILLEN, WHITE, ZELANO & BRANIGAN, P.C.<br>2200 CLARENDON BLVD.<br>SUITE 1400<br>ARLINGTON, VA 22201 |             |                      | MICHENER, JENNIFER KOLB |                  |
|   |             | ART UNIT             | PAPER NUMBER            |                  |
|   |             | 1762                 | 11                      |                  |

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|                        |                   |  |
|------------------------|-------------------|--|
| Application No.        | Applicant(s)      |  |
| 09/627,321             | DINKELBORG ET AL. |  |
| Examiner               | Art Unit          |  |
| Jennifer Kolb Michener | 1762              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 27 July 2000.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) 1-14, 17 and 19-27 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 15, 16 and 18 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                          | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                 | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group III, claims 15, 16, and 18, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that Examiner has not established that an undue searching burden would be involved in searching a broader scope of invention. This is not found persuasive because the art that would be used for each of the inventions is different than in any others. Furthermore the searches for each of the inventions are different and different issues will arise during prosecution of the different classes of inventions and the unrelated inventions. In regard to the statement that the search burden for the broader scope of invention would not be undue, Examiner speculates that Applicant is referring to the non-elected method claims. In which case, Examiner maintains that the non-elected method groups are unrelated to each other and to Group III. The searches required for each of the method inventions (i.e., a method of coating a stent with an ionic isotope, a method of coating a stent with a radio-labeled adhesive, and a method of coating a stent with gold and a thiol) would not fully encompass the search of the others.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 18 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. "Use" claims are directed to a non-statutory class of invention. For the purposes of examination, Examiner has examined the claim as a method claim directed to a method of coating a stent with the substances listed in claim 18, said stent useful in preventing restenoses.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis for the word "the" in the phrase "the adhesive" in line 2 of the claim.

Regarding the word "mixed" in line 3 of the claim, Examiner wishes to be certain that Applicant intended the adhesive-coated stent to be "mixed" in a solution of the isotope instead of "coated".

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (US 5,722,984).

Fischell teaches a method of coating a stent with an anti-thrombogenic agent and a radioactive isotope. The antithrombogenic agent may be a coating of phosphorylcholine. This chemical would act as an "adhesive", as is required in Applicant's claim. Alternatively, a first plastic layer containing a radioactive isotope may be used, such as polyethylene or Paralene. This plastic layer will act as an adhesive to adhere the radioactive isotope to the stent, as is required by the claim. (col. 1, line 38, col. 2, line 37). Fischell teaches that the radiation emitted from the treated stent reduces cell proliferation into the lumen of the stent following implantation, which inherently inhibits restenoses, as is required by the claim.

8. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Armini et al. (US 5,919,126).

Armini teaches coating a stent with an adhesion layer, followed by radioactive isotopes (abstract) to prevent restenoses (col. 1, line 38).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (US 5,722,984).

Fischell teaches a method of coating a stent with an anti-thrombogenic agent and a radioactive isotope, as is outlined above. Fischell teaches that phosphorylcholine is an anti-thrombogenic agent and phosphorous-32 is a radioisotope useful in coating stents (col. 1, lines 35-37). Therefore Fischell teaches a simple method of applying a phosphorylcholine coating to a stent wherein some of the phosphate groups contain radioisotope phosphorous 32, to create a single stent coating that is both antithrombogenic and radioactive (abstract; col. 1, lines 28-55; col. 2, lines 28-33). The phosphorylcholine acts as an adhesive, as required by Applicant, to bind the radioisotope to the stent surface.

While Fischell does not specifically teach the reaction step of radioactive phosphorus isotope with the organic phosphorylcholine adhesive agent, Examiner notes that the incorporation of the radioactive phosphorus into the phosphorylcholine adhesive inherently must occur prior to use of such chemical. Since P-32 is not the naturally occurring form of this element, Fischell must either react radioactive P-32 with the phosphorylcholine prior to use or obtain such a chemical from a manufacturer who did. In either case, the reaction step is inherent.

Following said reaction, the stent of Fischell is coated with the radio-labeled adhesive.

In regards to the claim limitation requiring method steps to occur at 0 °C-100 °C, it is Examiner's position that selection of a reaction temperature would be determined by one of ordinary skill in the art based on the reaction rates and heat stability of given chemical reactants. It would have been obvious to one having ordinary skill in the art to have determined the optimum value of a cause effective variable such as this through routine experimentation in the absence of a showing of criticality in the claimed variable.

*In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Furthermore, since Fischell does not provide any critical reaction or coating temperatures, it is Examiner's position that one of ordinary skill in the art intending to practice the invention of Fischell would have found it obvious to select room temperature as a first experimental trial temperature. Room temperature lies within Applicant's broad range of 0 °C-100 °C.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Armini et al. (US 5,919,126).

Armini et al. teach a process for making a radioactive stent by coating a non-radioactive stent with an adhesive layer, followed by coating with a radioactive isotope (abstract). Armini teaches throughout his specification the use of ion implantation to coat the stent with the isotope. In this method the radioactive isotope is provided in a gas stream. The isotope mixed in a gas would constitute a "solution" as required by the claim.

In regards to the claim limitation requiring coating to occur at 0 °C-100 °C, it is Examiner's position that selection of a process temperature would be determined by one of ordinary skill in the art based on the given chemicals used. It would have been obvious to one having ordinary skill in the art to have determined the optimum value of a cause effective variable such as this through routine experimentation in the absence of a showing of criticality in the claimed variable. *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Furthermore, since Armini does not provide a critical coating temperature of any kind, it is Examiner's position that one of ordinary skill in the art intending to practice the invention of Fischell would have found it obvious to select room temperature as a first experimental trial temperature. Room temperature lies within Applicant's broad range.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Strathearn et al. is cited for teaching a process of implanting radioisotopes on stents using chemical binding. Tam '249 and '320 are cited for teaching attachment of a radioactive isotope to a stent using a tie layer. Park is cited for teaching coating of a stent with a radionuclide in a sleeve. The sleeve would act as an adhesive.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-

306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener  
September 23, 2002



SHRIVE P. BECK  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700